

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 225, and 252

[Docket DARS-2023-0003]

RIN 0750-AL60

Defense Federal Acquisition Regulation Supplement: Restriction on Acquisition of Personal Protective Equipment and Certain

Items from Non-Allied Foreign Nations (DFARS Case 2022-D009)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule.

SUMMARY: DoD is issuing an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2022 that restricts the acquisition of personal protective equipment and certain other items from the Democratic People's Republic of North Korea, the People's Republic of China, the Russian Federation, and the Islamic Republic of Iran.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Comments on the interim rule should be submitted in writing to the address shown below on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2022-D009,

using any of the following methods:

- o Federal eRulemaking Portal: https://www.regulations.gov.
 Search for "DFARS Case 2022-D009." Select "Comment" and follow
 the instructions to submit a comment. Please include your name,
 company name (if any), and "DFARS Case 2022-D009" on any
 attached documents.
- o Email: osd.dfars@mail.mil. Include DFARS Case 2022-D009 in the subject line of the message.

Comments received generally will be posted without change to https://www.regulations.gov, including any personal information
provided. To confirm receipt of your comment(s), please check
https://www.regulations.gov, approximately two to three days
after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Bass, telephone 703-717-3446.

SUPPLEMENTARY INFORMATION:

I. Background

This interim rule revises the DFARS to implement section 802 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117-81) (10 U.S.C. 2533e) and section 881 of the NDAA for FY 2023 (Pub. L. 117-263). Section 802 adds the restriction to 10 U.S.C. 2533e (transferred to 10 U.S.C. 4875) that limits the acquisition of "covered items" (personal protective equipment and certain other items) from any of the following "covered countries": the Democratic People's Republic of North Korea, the People's Republic of China, the Russian

Federation, and the Islamic Republic of Iran, subject to exceptions. "Covered item" is defined as an article or item of-

- (1) Personal protective equipment for use in preventing spread of disease, such as by exposure to infected individuals or contamination or infection by infectious material including—
 - Nitrile and vinyl gloves;
 - Surgical masks;
- Respirator masks and powered air purifying respirators and required filters;
 - Face shields and protective eyewear;
- Surgical and isolation gowns and head and foot coverings; or
 - Clothing; and
- The materials and components thereof, other than sensors, electronics, or other items added to and not normally associated with, such personal protective equipment or clothing; or
- (2) Sanitizing and disinfecting wipes, testing swabs, gauze, and bandages.

Section 802 amends section 1870(d) of the NDAA for FY 2021

(Pub. L. 116-283) by providing for the future transfer of 10

U.S.C. 2533e to 10 U.S.C. 4875. However, the chapter that would have included 10 U.S.C. 2533e had already been repealed as part of the reorganization of the defense acquisition statutes (Title XVIII of the NDAA for FY 2021). As a result, section 2533e could not be added to title 10 of the U.S. Code. Section 881 of

the NDAA for FY 2023 adjusts the effective date of section 802(b) of the NDAA for FY 2022 to allow for the addition of section 2533e to title 10 and the subsequent transfer to 10 U.S.C. 4875.

II. Discussion and Analysis

A. Definitions

The interim rule adds a definition at DFARS 225.7023-1,

Definitions, for "covered item" and adds the definition of

"covered country" at 225.7001, Definitions. The restriction

limits the acquisition of a covered item from a covered country,

subject to exceptions.

The definition of "covered country" applies to this rule and continues to apply to the restriction at DFARS 225.7018 on the acquisition of certain magnets, tantalum, and tungsten.

Accordingly, the definition of "covered country" is moved from DFARS section 225.7018-1 to 225.7001 to apply at the subpart level.

B. Restriction

The restriction on the acquisition of a covered item from a covered country is added at DFARS 225.7023-2 in accordance with the requirements of section 802 of the NDAA for FY 2022.

C. Exceptions

The exceptions to the restriction at DFARS 225.7023-2 are added at DFARS 225.7023-3. The restriction does not apply to an acquisition for: (1) a covered item for use outside of the United States; (2) acquisitions at or below \$150,000; or (3) if

the head of the contracting activity determines that a covered item of satisfactory quality and quantity, in the required form, cannot be procured as and when needed from nations other than a covered country to meet requirements at a reasonable price.

D. Contract Clause

A new clause is added at DFARS 252.225-7061, Restriction on the Acquisition of Personal Protective Equipment and Certain Other Items from Non-Allied Foreign Nations, for use in solicitations and contracts, including solicitations and contracts using Federal Acquisition Regulation (FAR) part 12 procedures for the acquisition of commercial items, with an estimated value above \$150,000 that are for the acquisition of covered items and are for use within the United States.

This rule also adds the new clause 252.225-7061, Restriction on the Acquisition of Personal Protective Equipment and Certain Other Items from Non-Allied Foreign Nations, to the list of solicitation provisions and contract clauses for the acquisition of commercial items at DFARS 212.301(f).

III. Applicability to Contracts at or Below the Simplified
Acquisition Threshold (SAT) and for Commercial Products,
Including Commercially Available Off-the-Shelf (COTS) Items, and
Commercial Services

This rule creates a new contract clause at 252.225-7061,

Restriction on the Acquisition of Personal Protective Equipment and Certain Other Items from Non-Allied Foreign Nations. The clause at DFARS 252.225-7061 is prescribed at DFARS 225.7023-4

for use in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items, with an estimated value above \$150,000 that are for the acquisition of covered items for use within the United States. DoD is applying the rule to contracts valued above \$150,000 but at or below the SAT. DoD is applying the rule to contracts for the acquisition of commercial items, including COTS items.

A. Applicability to Contracts at or Below the Simplified Acquisition Threshold

41 U.S.C. 1905 governs the applicability of laws to contracts or subcontracts in amounts not greater than the simplified acquisition threshold. It is intended to limit the applicability of laws to such contracts or subcontracts. 41 U.S.C. 1905 provides that if a provision of law contains criminal or civil penalties, or if the Federal Acquisition Regulatory Council makes a written determination that it is not in the best interest of the Federal Government to exempt contracts or subcontracts at or below the SAT, the law will apply to them. The Principal Director, Defense Pricing and Contracting (DPC), is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the FAR system of regulations. DoD has made that determination. Therefore, this rule applies to contracts valued above \$150,000 but at or below the SAT.

B. Applicability to Contracts for the Acquisition of Commercial Products, Including COTS Items, and Commercial Services

10 U.S.C. 3452 exempts contracts and subcontracts for the acquisition of commercial products, including COTS items, and commercial services from provisions of law enacted after October 13, 1994, unless the Under Secretary of Defense (Acquisition and Sustainment) (USD(A&S)) makes a written determination that it would not be in the best interest of DoD to exempt contracts for the procurement of commercial products and commercial services from the applicability of the provision or contract requirement, except for a provision of law that—

- Provides for criminal or civil penalties;
- Requires that certain articles be bought from American sources pursuant to 10 U.S.C. 4862, or that strategic materials critical to national security be bought from American sources pursuant to 10 U.S.C. 4863; or
- Specifically refers to 10 U.S.C. 3452 and states that it shall apply to contracts and subcontracts for the acquisition of commercial products (including COTS items) and commercial services.

The statute implemented in this rule does not impose criminal or civil penalties, does not require purchase pursuant to 10 U.S.C. 4862 or 4863, and does not refer to 10 U.S.C. 3452.

Therefore, section 802 of the NDAA for FY 2022 will not apply to the acquisition of commercial services or commercial products including COTS items unless a written determination is made.

Due to delegations of authority, the Principal Director, DPC is the appropriate authority to make this determination. DoD has made that determination. Therefore, this rule applies to the acquisition of commercial products, including COTS items.

C. Determination

Although section 802 of the NDAA for FY 2022 does not refer to 10 U.S.C. 3452 and state that it shall apply to contracts and subcontracts for the acquisition of commercial products (including COTS items) and commercial services, it is the clear intent of the statute to cover commercial products and commercial services other than those specifically excepted.

Personal protective equipment is mainly commercial. Therefore, section 802 should apply to contracts for the acquisition of commercial products including COTS items and commercial services for acquisitions above \$150,000.

Decreasing DoD's dependence on personal protective equipment and other items identified in section 802 that originate in the covered countries is a matter of public health and national security. As a matter of national security, the domestic supply chain for personal protective equipment and certain other items identified in section 802 is critical, and adequate continued supply of personal protective equipment and certain other items is vital to ensure domestic control with minimal disruption in production. Eradicating counterfeit items within the domestic supply chain is required to accommodate the demand for both DoD

military use and nonmilitary Government requirements that DoD supports.

A shortage of supply of personal protective equipment and certain other items would put at risk public health and the safety and well-being of the general public and would hinder DoD's mission readiness. Restricting acquisition from the covered countries will promote growth in domestic capability and reduce dependence on foreign sources that are not our allies. An exception for contracts for the acquisition of commercial products, including COTS items, would exclude the contracts intended to be covered by the law, thereby undermining the overarching public policy purpose of the law.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801-808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VI. Regulatory Flexibility Act

DoD does not expect this interim rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. However, there may be minor compliance costs to validate the origin of covered items, materials, and components. An initial regulatory flexibility analysis has been performed and is summarized as follows:

This rule is required to implement section 802 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117-81) (10 U.S.C. 2533e, transferred to 10 U.S.C. 4875).

The objective of the rule is to implement the restriction provided by section 802 on the acquisition of a covered item, defined as an article or item of personal protective equipment for use in preventing the spread of disease, such as by exposure to infected individuals or contamination or infection by

infectious material, or other items for sanitizing and disinfecting, testing, gauze, and bandages, from the Democratic People's Republic of North Korea, the People's Republic of China, the Russian Federation, or the Islamic Republic of Iran.

Based on data from the Federal Procurement Data System for FY 2019, 2020, and 2021, DoD awarded an average of 1,677 contracts in the United States that equaled or exceeded \$150,000 in value and were for the acquisition of medical, dental, veterinary equipment and supplies (excluding covered items for use outside the United States). These contracts were awarded to 192 unique entities, of which 105 were small entities. It is not known what percentage of these awards might involve personal protective equipment and other materials and components from the Democratic People's Republic of North Korea, the People's Republic of China, the Russian Federation, or the Islamic Republic of Iran.

There are no projected reporting or recordkeeping requirements. However, there may be minor compliance costs to validate with suppliers the origin of covered items, materials, and components.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

In accordance with section 802, DoD is excepting acquisitions-

- Equal to or less than \$150,000;
- For covered items for use outside the United States; and

• If a covered item of satisfactory quality and quantity is not available in the required form from nations other than the Democratic People's Republic of North Korea, the People's Republic of China, the Russian Federation, or the Islamic Republic of Iran.

DoD was unable to identify any other alternatives that would reduce burden on small businesses and still meet the objectives of the statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (DFARS Case 2022-D009), in correspondence.

VII. Paperwork Reduction Act

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

VIII. Determination to Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense that urgent and compelling reasons exist to promulgate this interim rule without prior opportunity for public comment. This action is necessary because section 802

adds the restriction in 10 U.S.C. 2533e (transferred to 10 U.S.C. 4875), with certain exceptions, that DoD may not acquire covered items of personal protective equipment (PPE) and certain other items from any of the following covered countries: the Democratic People's Republic of North Korea; the People's Republic of China; the Russian Federation; and the Islamic Republic of Iran.

Implementation of this restriction is urgent, because the law was effective upon enactment. Decreasing DoD's dependence on PPE and other items as identified in section 802 that originate in the covered countries is a matter of public health and national security. PPE is mainly commercial. It is a matter of national security to reduce U.S. dependence on the covered countries, because the domestic supply chain for PPE and certain other items is critical, and adequate continued supply of PPE and certain other items is vital to ensure domestic control with minimal disruption in production. Eradication of counterfeit items within the domestic supply chain is required to accommodate the demand for both DoD military use and nonmilitary Government requirements that DoD supports and to ensure DoD's mission readiness.

A shortage of supply of PPE and certain other items would put at risk public health and the safety and well-being of the general public and would hinder DoD's mission readiness.

Restricting acquisition of these items from covered countries

will promote growth in domestic capability and reduce dependence on foreign sources that are not our allies.

However, pursuant to 41 U.S.C. 1707 and FAR 1.501-3(b), DoD will consider public comments received in response to this interim rule in the formation of the final rule.

List of Subjects in 48 CFR Parts 212, 225, and 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 225, and 252 are amended as follows:

1. The authority citation for 48 CFR parts 212, 225, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

- 2. Amend section 212.301 by adding paragraph (f)(x)(MM) to read as follows:
- 212.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

* * * * *

- (f) * * *
- (x) * * *
- (MM) Use the clause at 252.225-7061, Restriction on the Acquisition of Personal Protective Equipment and Certain Other Items from Non-Allied Foreign Nations, as prescribed in

225.7023-4, to comply with section 802 of the National Defense Authorization Act for Fiscal Year 2022 (Pub. L. 117-81) (10 U.S.C. 4875).

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PART 225-FOREIGN ACQUISITION

3. Amend section 225.7001 by adding a definition of "Covered country", in alphabetical order, to read as follows:

225.7001 Definitions.

* * * * *

Covered country means-

- (1) The Democratic People's Republic of North Korea;
- (2) The People's Republic of China;
- (3) The Russian Federation; and
- (4) The Islamic Republic of Iran (10 U.S.C. 4872 and 4875).

* * * * *

225.7018-1 [Amended]

- 4. Amend section 225.7018-1 by removing the definition of "Covered country".
- 5. Add sections 225.7023, 225.7023-1, 225.7023-2, 225.7023-3, and 225.7023-4 to read as follows:

* * * * *

Sec.

225.7023 Restriction on acquisition of personal protective equipment and certain other items from non-allied foreign nations.

225.7023-1 Definitions.

225.7023-2 Restriction.

225.7023-3 Exceptions.

225.7023-4 Contract clause.

* * * * *

225.7023 Restriction on acquisition of personal protective equipment and certain other items from non-allied foreign nations.

225.7023-1 Definitions.

As used in this section-

Covered item means an article or item of-

- (1) Personal protective equipment for use in preventing spread of disease, such as by exposure to infected individuals or contamination or infection by infectious material, including—
 - (i) Nitrile and vinyl gloves;
 - (ii) Surgical masks;
- (iii) Respirator masks and powered air purifying
 respirators and required filters;
 - (iv) Face shields and protective eyewear;
- (v) Surgical and isolation gowns and head and foot coverings; or
 - (vi) Clothing; and
- (vii) The materials and components thereof, other than sensors, electronics, or other items added to and not normally associated with such personal protective equipment or clothing; or
- (2) Sanitizing and disinfecting wipes, testing swabs, gauze, and bandages.

225.7023-2 Restriction.

Except as provided in 225.7023-3, do not acquire a covered item from a covered country in accordance with section 802 of the National Defense Authorization Act for Fiscal Year 2022 (Pub. L. 117-81) (10 U.S.C. 4875).

225.7023-3 Exceptions.

The restriction in section 225.7023-2 does not apply to acquisitions-

- (a) Of covered items for use outside of the United States;
- (b) At or below \$150,000; or
- (c) (1) If the head of the contracting activity determines that a covered item of satisfactory quality and quantity, in the required form, cannot be procured as and when needed from nations other than a covered country to meet requirements at a reasonable price.
- (2) The contracting officer shall include a copy of any such determination in the contract file.

225.7023-4 Contract clause.

Unless an exception applies, use the clause at 252.225-7061, Restriction on the Acquisition of Personal Protective Equipment and Certain Other Items from Non-Allied Foreign Nations, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products, including COTS items, and commercial services, and that—

- (a) Are for the acquisition of covered items;
- (b) Are for use within the United States; and

(c) Have an estimated value greater than \$150,000.

PART 252-SOLICITATION PROVISIONS AND CONTRACT CLAUSES

6. Add section 252.225-7061 to read as follows:

252.225-7061 Restriction on the Acquisition of Personal Protective Equipment and Certain Other Items from Non-Allied Foreign Nations.

As prescribed in 225.7023-4, use the following clause:

RESTRICTION ON THE ACQUISITION OF PERSONAL PROTECTIVE EQUIPMENT

AND CERTAIN OTHER ITEMS FROM NON-ALLIED FOREIGN NATIONS (JAN

2023)

- (a) Definitions. As used in this clause—
 Covered country means—
 - (1) The Democratic People's Republic of North Korea;
 - (2) The People's Republic of China;
 - (3) The Russian Federation; and
 - (4) The Islamic Republic of Iran.

Covered item means an article or item of-

- (1) Personal protective equipment for use in preventing spread of disease, such as by exposure to infected individuals or contamination or infection by infectious material, including—
 - (i) Nitrile and vinyl gloves;
 - (ii) Surgical masks;
- (iii) Respirator masks and powered air purifying
 respirators and required filters;
 - (iv) Face shields and protective eyewear;

- (v) Surgical and isolation gowns and head and foot coverings; or
 - (vi) Clothing; and
- (vii) The materials and components thereof, other than sensors, electronics, or other items added to and not normally associated with such personal protective equipment or clothing; or
- (2) Sanitizing and disinfecting wipes, testing swabs, gauze, and bandages.
- (b) Restriction. The Contractor shall not deliver under this contract a covered item from a covered country (10 U.S.C. 4875).
- (c) Subcontracts. The Contractor shall insert this clause, including this paragraph (c), without alteration other than to identify the appropriate parties, in subcontracts valued above \$150,000 that are for the acquisition of covered items, including subcontracts for commercial products, including commercially available off-the-shelf items, and commercial services.

(End of clause)

[FR Doc. 2023-01295 Filed: 1/30/2023 8:45 am; Publication Date: 1/31/2023]